



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,941	07/25/2003	Pamela T. Manning	01073/I US	3233

7590 11/17/2005
Pharmacia Corporation
Corporate Patent Department
P.O. Box 1027
Chesterfield, MO 63006

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT PAPER NUMBER

1614

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,941

Applicant(s)

MANNING ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-30, 32-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-30 and 32-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Request for Continued Prosecution (RCE) filed October 28, 2005 is acknowledged and accepted. Claims 2 and 31 are canceled. Claims 1, 3-30 and 32-43 remain under consideration.

A new title is noted. It is further noted the term "prevention" in claim one, as well as references to a "prodrug" in claims 1, 14, 17, 22 and 25, are deleted.

In the last Office Action the disclosure was objected to for various informalities. Following the deletion of a description of compounds of instant Formula II, an objection to the disclosure is withdrawn. The assertion that the designations "2HCl" and "2TFA" are dangling, is withdrawn because to a chemist of ordinary skill in the art, the depiction is proper and readily recognizable. The objection is withdrawn.

In response to the rejection of claims 1-43 under the judicially created doctrine of obviousness-type double patenting set forth in the last Office Action, a Terminal Disclaimer has been filed and was accepted. Accordingly, the rejection is withdrawn.

Claims 1-43 remained rejected under 35 U.S.C. 112, first paragraph, in the last Office Action, for the reasons set forth in the First Action. Methods of assaying efficacy of iNOS inhibitors in gastric epithelial cells and pharmaceutical compositions do not provide support for methods of treating inflammatory bowel disease, Crohn's disease, ulcerative colitis, peptic ulcer disease, gastric ulceration, gastritis, ileitis, gastroesophageal reflux disease, irritable bowel syndrome, paralytic ileus and diarrhea. Table I demonstrates that various nitric oxide synthase inhibitors decrease the rise in plasma nitrite/nitrate levels as an indication of nitric oxide production induced by endotoxin. Table II shows an ability of various compounds of the present invention to

Art Unit: 1614

inhibit inducible nitric oxide synthase activity *in vivo*. Further, the unpredictability observed with single agent therapy is compounded when a combination of agents is employed, as required by claims 14-43.

The rejection of claims 1, 3-30 and 32-43 under 35 U.S.C. 112, first paragraph, is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low can be reached on 591-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 10, 2005


Phyllis G. Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**